

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

FEB 25 2011

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1. Submitter's Information: 21 CFR 807.92(a)(1)**

MEDISON CO., LTD.  
1003, Daechi-dong, Gangnam-gu,  
Seoul 135-280, Korea

**Contact Person:**  
Kyeong-Mi, Park  
Regulatory Affairs Manager

Telephone: 82.2.2194.1373  
Facsimile: 82.2.556.9209

**Data Prepared:** August 12, 2010

**2. Name of the device:**Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

ACCUVIX XG Diagnostic Ultrasound System

Classification Names:

	<u>FR Number</u>	<u>Product Code</u>
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

**3. Identification of the predicate or legally marketed device:**

K101455, EKO 7 Diagnostic Ultrasound System  
K092159, ACCUVIX V20 Diagnostic Ultrasound System

#### 4. Device Description:

The ACCUVIX XG is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as B mode, M mode, Color Doppler imaging, Power Doppler imaging, PW/CW Spectral Doppler mode, Harmonic imaging, Tissue Doppler imaging, 3D imaging mode (real time 4D imaging mode) or as a combination of these modes. The ACCUVIX XG also gives the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The ACCUVIX XG has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

The ACCUVIX XG has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment
- NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993-1, Biocompatibility

#### 5. Intended Uses:

The ACCUVIX XG Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Intra-operative, Pediatric, Small Organs, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel.

#### 6. Technological Characteristics:

The ACCUVIX XG is substantially equivalent to the ACCUVIX V20 Diagnostic Ultrasound System, cleared via K092159, and the EKO 7 Diagnostic Ultrasound System, cleared via K101455. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

**END of 510(K) Summary**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Medison Co., Ltd.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

FEB 25 2011

Re: K103397  
Trade/Device Name: ACCUVIX XG Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYO, ITX, and IYN  
Dated: February 8, 2011  
Received: February 10, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACCUVIX XG Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>C1-4EC</u>	<u>VR5-9</u>	<u>P2-4BA</u>	<u>V5-9</u>
<u>C2-61C</u>	<u>L3-8</u>	<u>P3-8CA</u>	<u>V6-12</u>
<u>C4-9/10ED</u>	<u>L5-131S</u>	<u>P4-12</u>	<u>CW2.0</u>
<u>ER4-9/10ED</u>	<u>LF5-12</u>	<u>3DC2-6</u>	<u>CW4.0</u>
<u>EV4-9/10ED</u>	<u>LS5-13</u>	<u>V4-8</u>	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Mary Pastel", is written over a horizontal line.

Mary Pastel, ScD.  
Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure(s)

### SECTION 1.3 INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

Device Name: ACCUVIX XG Diagnostic Ultrasound System

Indications for Use: \_\_\_\_\_

The ACCUVIX XG Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

The clinical applications include: Fetal, Abdominal, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Indications for Use

Mary S Patel  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
510K-103397

Section 1.3, page 1

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: ACCUVIX XG Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	N	N	N		N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N	N	N	Note 1	Notes 4, 7
	Intra-operative (See Note 6)	N	N	N		N	Note 1	Notes 8, 9
	Intra-operative (Neuro.)	N	N	N		N	Note 1	Notes 8, 9
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 10
	Small Organ (See Note 5)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 10
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2, 7, 8, 9
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8, 10
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 10
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 7, 8, 9, 10
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note 1	Note 2, 5, 6, 7, 9, 10
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

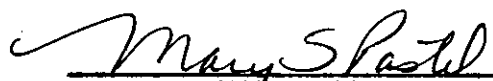
Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

Indications for Use

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3, page 2

510K 103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C1-4EC for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

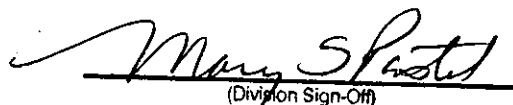
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

Section 1.3, page 3

510K 103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C2-6IC for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

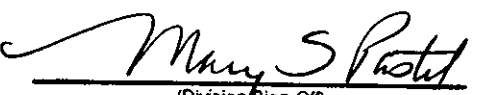
Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

Indications for Use

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3, page 4

510K 103397



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: C4-9/10ED for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ (See Note 5)	P	P	P		P	Note 1	Notes 2, 7, 8
	Neonatal Cephalic	P	P	P		P	Note 1	Notes 2, 7, 8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Notes 2, 7, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

Section 1.3, page 5

510K 103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: ER4-9/10ED for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+W, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

Section 1.3, page 6

510K 102397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: EV4-9/10ED for use with ACCUVIX XG.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & II)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+W, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

Section 1.3, page 7

510K 103297

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: VR5-9 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Note 2, 7, 8, 10
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 7, 8, 10
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

Indications for Use

  
(Division Sign-Off)  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Section 1.3, page 8

510K

103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L3-8 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

Indications for Use

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

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103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: L5-131S for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

Indications for Use

Division of Radiological Devices  
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103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LF5-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9, 10
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Note 10: ElastoScan

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: LS5-13 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)	P	P	P		P	Note 1	Note 8, 9
	Intra-operative (Neuro.)	P	P	P		P	Note 1	Note 8, 9
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 8, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 8, 9
	Neonatal Cephalic	P	P	P		P	Note 1	Note 8, 9
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 8, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 8, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K093849; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: P2-4BA for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I only)	Clinical Application Specific (Tracks I & III)	Mode of Operation (*includes simultaneous B-mode)						
		B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+W, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: P3-8CA for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: P4-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Small Organ (See Note 5)							
	Neonatal Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1	Note 4, 7
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K101455; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

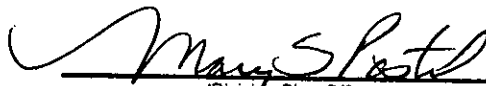
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
 Prescription Use (Per 21 CFR 801.109)



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510K 103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: 3DC2-6 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track 1 only)	Specific (Tracks I & II)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K093714; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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510K 103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V4-8 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V5-9 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 7, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



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510K-103397

# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: V6-12 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Small Organ (See Note 5)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 7, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6, 7, 9
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

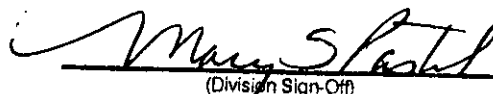
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

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510K 103397

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW2.0 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+CW, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

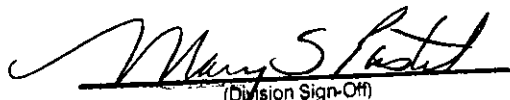
Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)

  
(Division Sign-Off)

Division of Radiological Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

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510K 103397



# DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:

Device Name: CW4.0 for use with ACCUVIX XG

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal (See Note 3)							
	Abdominal							
	Intra-operative (See Note 6)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric				P			
	Small Organ (See Note 5)							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)							

N= new indication; P= previously cleared by FDA K092159; E= added under Appendix E

**Additional Comments:**

Color Doppler includes Power (Amplitude) Doppler

Note 1: B+M, B+PW, B+C, B+PD, B+C+W, B+C+PW, B+PD+PW, B+C+M, Dual B, Dual B+C, Dual B+PD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRII, Office of In Vitro Diagnostic Devices (OIVD)  
Prescription Use (Per 21 CFR 801.109)



(Division Sign-Off)

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Office of In Vitro Diagnostic Device Evaluation and Safety

Indications for Use

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103397